

DRAFT STATEMENT OF WORK
CHEMICAL REVIEW AND EVALUATION

I. **BACKGROUND**

The Office of Pollution Prevention and Toxics (OPPT) of the Environmental Protection Agency (EPA) is responsible for the evaluation of chemical substances under the Toxic Substances Control Act (TSCA). Under Section 5 of the Act, the EPA may evaluate new chemical substances (i.e, chemicals not listed on the TSCA Chemical Substance Inventory) for their stated uses, their potential new uses, and potential risks associated with those uses. Existing chemicals evaluated under Sections 4 and 6 of TSCA may also be evaluated for the potential risks associated with their various uses. In these cases, the EPA may develop regulatory requirements to protect humans and the environment from injury resulting from manufacture, processing, intended and potential new uses, and disposal of existing and new chemical substances and their metabolites.

The contractor shall support OPPT by performing chemistry evaluations of new and existing chemicals including the chemistry aspects of their manufacture, processing, use, potential new uses, and pollution prevention. In performing such evaluations, the contractor shall be required to gather, generate, evaluate, and communicate chemistry and chemical technology information for a wide variety of chemical substances including substances prior to manufacture for commercial purposes (for which there may be little or no published data) as well as substances which are established in U.S. Commerce and therefore may have extensive literature references. This responsibility also includes determination of potential other uses for these substances and their substitutes.

In addition to providing a review of Premanufacture Notices (PMNs) for establishing the identity of the PMN substance, its physical/chemical properties, the basic chemistry, potential new uses and related chemicals, the contractor may also be required provide a pollution prevention assessment involving characterization and quantification of the waste produced from the manufacturing processes of PMN substances preselected by EPA for review. The contractor will compare the information in the PMN submission and provided by the submitter to technical criteria established by EPA in order to determine whether concerns exist regarding types and amounts of waste associated with a given manufacturing process. The contractor may also be required to determine possible causes for the waste produced and for suggesting approaches for its reduction and/or process alteration. The contractor may be required to analyze

alternative synthetic chemical reactions or synthetic pathways.

"Chemistry and chemical technology information" includes detailed chemical identity such as chemical name and chemical structure, clarification of identity data, composition, chemical and physical properties, chemical reactions including in vivo reactivity, chemical processing, stoichiometry, byproducts, impurities, feedstocks, and information pertaining to a full understanding of the use of a chemical substance for the purposes of classifying and coding the use data as well as for assessing human exposure, environmental release, and chemical market impacts. This information may be required on the principal chemical substance(s) or on associated substances such as precursors, derivatives, feedstocks, byproducts, impurities, and similar substances. A new fields of interest develop, like biotechnology and nanotechnology, the contractor may be asked to research these areas as well.

"Information gathering" includes planning, conducting, and reviewing technical information searches (including the published chemistry literature, chemical reference series, chemistry texts, chemistry experts where appropriate, chemical data bases and TSCA Confidential Business Information (CBI) files which will be available at EPA Headquarters.

"Report generation" includes the actions necessary to provide chemistry and chemical technology information. Report generation also includes identifying and supplying information that is missing, incomplete, or incorrect and may involve calculations, extrapolations, modeling, and estimations using chemical analogs and predictive methodologies.

"Information evaluation" includes validating, verifying, clarifying, correlating, classifying, summarizing, and interpreting chemistry and chemical technology information.

"Information communication" includes preparing reports, making oral presentations, actively participating in meetings, and performing related administrative duties, such as database maintenance and database entry.

The principal users of this technical support are the assessors who carry out risk and economic impact assessments, including assessors of health and environmental effects, human exposures, environmental releases, and marketing and social ramifications, as well as those who make integrated regulatory decisions.

II. SCOPE OF WORK

This contract may require the Contractor to research, evaluate, and analyze data and information in connection with chemical review and evaluation and other areas as specified in the Statement of Work. It may require the Contractor to conduct market research, conduct analysis and provide policy options. The foregoing is not an exhaustive list of the situations contemplated by the Statement of Work. The Contractor shall fully substantiate and document all of its work effort in this regard so that EPA may critically analyze and approve/disapprove any recommendations, options, alternatives or courses of action flowing from the Contractor's work effort.

For such situations, the Contractor shall adhere to the following general requirements:

General Requirements:

(1) In evaluating and performing the services required under this Statement of Work, the Contractor shall submit all relevant information used in developing conclusions or options to the responsible Work Assignment Manager (WAM) for all projects for review and approval.

(2) All reports, drafts, papers, etc. prepared by the contractor shall be submitted in draft form. The Contractor shall submit the completed draft to the responsible WAM for review and approval. The drafts submitted shall include copies of the literature cited or make reference to all citations in the document for WAM's verification and approval.

(3) When in attendance at meetings, the Contractor's attendance shall be limited to that portion of the activity for which the contractor is required in order to meet the requirements of the SOW. The Contractor personnel shall identify itself as contractor personnel in all activities associated with work performed under the SOW, and in attendance at meetings in conjunction with activities associated with the SOW requirements.

(4) Reports submitted by the Contractor that contain recommendations to the Agency, will explain and rank alternatives, if any; describe the deliberation; report any dissenting views; list the sources relied upon, and make clear the methods and considerations upon which the recommendations are based. All final decisions will be made by EPA.

(5) When working with, transporting, or storing TSCA CBI, the Contractor must adhere to all the requirements of the current TSCA CBI Security Manual.

(6) The following documentation is required from offerers:

* A Quality Management Plan(QMP) must be submitted using the specifications provided in "EPA Requirements for Quality Management Plans, QA/R-2, EPA, 1998".

* A Quality Assurance Plan(QAP) must be submitted following the specifications in EPA Requirements for Quality Assurance Projects Plans(QAPPs), QA/R-5, EPA, 1998".

The EPA Quality Staff web page can be found at:

<http://www.epa.gov/quality>

III. **TASKS**

To perform the tasks described below, the contractor is required to have the following capabilities, knowledge, and experience:

(a) the ability to insure the continuous availability of five to seven chemists during the life of the contract up to full time for this contract with the following qualifications:

(i) training completed at the Ph.D. level in organic or physical organic chemistry for the five to seven chemists;

(ii) knowledge of organic chemical documentation and the scientific literature, organic chemical synthesis, organic chemistry reaction mechanisms, chemical structure and chemical and physical property relationships, uses of chemicals and structure/function relationships, chemicals in U.S. commerce, industrial chemical practices and technologies, and Green chemistry Principles and Practices, including environmentally benign alternative synthesis;

(iii) skills in investigating, predicting, evaluating, and communicating chemical information, including a working knowledge of computer software programs (such as ISIS/Base, ISIS/Draw, CAS Online, Accelrys Accord, Microsoft Access, Lotus Notes, Microsoft Excel, Lotus 1-2-3, dBase, Beilstein Online, ChemBase, ChemText) and experience and skill in presenting technical data;

(iv) ability to identify structural and functional chemical analogs and to make professionally based judgements regarding chemical and physical properties, validity of intended uses, the potential for new uses for new chemical substances, and the potential for alternative synthetic routes to prevent pollution; and

(v) experience in synthesis or manufacture of organic and inorganic chemicals, in chemical research and development, and in applications of organic chemicals;

(b) demonstrated freedom from real, apparent, or potential conflicts of interest relating to TSCA Confidential Business Information (CBI) and demonstrated ability to handle CBI per TSCA CBI procedures and regulations;

(c) ability to begin work on cases identified daily within two to four hours, complete work within two to four days, attendscheduled semi-weekly meetings as well as unscheduled meetings involving personal interaction with EPA's PMN review staff, and carry out work two to five days per week at EPA Headquarters or at a contractor office location in close proximity to EPA's Offices in Washington, D.C. to allow for efficient travel to EPA Headquarters for meetings and use of CBI facilities such that travel time is minimized and the security of CBI documents is not put at unnecessary risk during transport; and

(d) demonstrated quality assurance and control for work performed under the contract.

As specified in individual work assignments, the following items are representative of the tasks to be performed:

1. Chemical Review and Search Strategies (CRSS) Chemistry Report

The CRSS meeting is an early disposition meeting in the PMN review process. The CRSS chemistry report documents validate chemical identity, synthetic routes, feedstocks, byproducts, impurities, catalysts, solvents, reagents, potential Persistent, Bioaccumulative, and Toxic (PBT) substances, formulations, physical and chemical properties, intended uses and potential other uses, potential for pollution prevention or pollution reduction, and other pertinent data necessary for the review of the case for unreasonable risks. The contractor shall be required to read, understand, evaluate, correct, develop supplemental data, summarize, and prepare electronic reports on the chemistry and chemical technology information on new chemical substances. Certain of this information may be contained in documents submitted under Section 5 of TSCA: Premanufacture Notices (PMNs), including Test Market Exemption Applications (TMEAs), Section 5 (h)(4) notices or applications, or other notices or application received, specifically under Sections 5 or 8.

Upon receipt of an assignment, the contractor shall prepare a report which shall include an estimate of the accuracy of chemical identity, physical/chemical properties, chemical synthesis, pollution prevention potential, and use information based on consistency and completeness of information. The contractor shall also search EPA generated databases for

structural analogs that may have been previously reviewed or the contractor may be required to perform an additional search utilizing the published chemistry literature (journals, chemistry texts, handbooks and other chemistry reference volumes, Beilstein, Kirk-Othmer, etc.) for existing information on the chemical or its analogs. All intended and possible new uses of the PMN chemicals shall be determined and evaluated. The results of the use determination shall be included in the chemistry report. The contractor shall also identify and address important data gaps or other missing information that may provide insight into the processing, use, potential additional uses, or disposal of the PMN substance or related chemicals. Errors, data gaps, or uncertainties shall be discussed with the WAM or the coordinating EPA staff chemist(s) who will ascertain whether additional information or clarification from the submitter is needed. The contractor shall also attempt to develop or estimate important and necessary information using appropriate methods of estimation or extrapolation. Appropriate information gathering, generating, evaluating, summarizing, and communicating shall be done by the contractor to provide a full understanding of the chemical's identity, properties, synthesis, toxic waste, and its planned or potential uses in commerce from a chemist's perspective. Information on the substance shall also be characterized and summarized in a final report.

The timing of the chemistry support and deliverables provided are critical to adequate performance under this contract. In the chemistry review of Premanufacture Notices, the major portion of the work to be performed by a contractor shall commence within two to four hours of the assignment, and shall be completed (including an electronic report and formal oral presentation) within two to four days after receipt of the assignments. PMNs are received by EPA at any time during each working day; accordingly, cases to be reviewed could be identified and assigned at any time. In addition to the individual evaluation tasks, the contractor shall also be required to participate directly in regularly scheduled meetings two to five days per week at the EPA offices in Washington, D.C. Certain of these meetings occur in a twice-a-week cycle. Because of the nature of the scheduling, the nature of the technical support function, the restricted availability of source documents (currently restricted to Monday-Friday, 8:30 AM to 4 PM), and the rapid response requirements, the contractor shall be readily available to respond to assignments within the time constraints stated above.

The Agency will screen incoming PMNs to determine which PMN cases will receive full Agency review (non-drop cases) and which cases will not receive further review (drop cases). Presentations, including structural diagrams, shall be made by

the contractor on assigned non-drop cases usually within three days after assignment twice-a-week in early morning meetings at EPA headquarters. The electronic chemistry reports, in a prescribed format, shall be due by 11:00 AM on the day of presentation at the Chemical Review and Search Strategies (CRSS) meetings. Any changes that need to be made to the chemistry reports after the CRSS meeting should be made with the concurrence of the EPA liaison chemist or at the direction of the EPA chemist in charge. Corrected versions of the electronic report should be delivered (1) the same day for reports that were presented at the CRSS meeting, (2) within 7 calendar days of the assignment for reports that have completed their CRSS meeting review or (3) within one day after a Focus meeting (an early disposition meeting in the PMN review process) standard review decision. (Focus meetings are held twice a week at EPA.) If there have been no changes to the electronic copy of the report on the day of the CRSS meeting, this will serve as the final version. This should include the work and reports for the case on pollution prevention or pollution reduction in the area of New Chemicals. Additional review and liaison work may be required subsequent to the presentation and may lead to changes or corrections to the chemistry reports. All modifications to the reports shall be completed within the specified time limit.

To perform the above work, the contractor shall be required to have the following capabilities, knowledge, and experience: (1) the ability to insure the continuous availability of five to seven chemists during the life of the contract up to full time for this contract with the following qualifications: (a) training completed at the Ph.D. level in organic or physical organic chemistry; (b) significant knowledge of organic chemical documentation and the scientific literature, organic chemical synthesis, organic chemistry reaction mechanisms, chemical structure and chemical and physical property relationships, uses of chemicals and structure/function relationships, chemicals in U.S. Commerce, industrial chemical practices and technologies and environmentally benign alternative syntheses; (c) skills in investigating, predicting, evaluating, and communicating chemical information, including a working knowledge of computer software programs (such as ISIS/Base, ISIS/Draw, CAS Online, Synopsys Accord, Microsoft Access, Lotus Notes, Microsoft Excel, Lotus 1-2-3, dBase, Beilstein Online, ChemBase, Chemtext) and experience and skill in presenting technical data; (d) ability to identify structural and functional chemical analogs and to make professionally based judgments regarding chemical and physical properties, validity of intended uses, the potential for new uses for new chemical substances, and the potential for alternative synthetic routes to prevent pollution; and (e) experience in synthesis or manufacture of organic and inorganic chemicals, in chemical research and development, and in applications of organic

chemicals; (2) demonstrated freedom from real, apparent, or potential conflicts of interest relating to TSCA Confidential Business Information (CBI) and demonstrated ability to handle CBI per TSCA CBI procedures and regulations; (3) ability to begin work on cases identified daily within two to four hours, complete work within two to four days, attend scheduled semi-weekly meetings as well as unscheduled meetings involving personal interaction with EPA's PMN review staff, and carry out work two to five days per week at EPA Headquarters or at a contractor office location in close proximity to EPA's offices in Washington, D.C. to allow for efficient travel to EPA Headquarters for meetings and use of CBI facilities such that travel time is minimized and the security of CBI documents is not put at unnecessary risk during transport; and (4) demonstrated quality assurance and control for work performed under the contract.

2. Standard Review, PMN Chemistry Report

These reports are designed to concentrate and expand on specific information needs identified during and after the Focus Meeting, an early disposition meeting in the PMN Review Process. As such, these reviews may take various forms, e.g., more information in one or more particular subject areas, e.g., rate of hydrolysis of the subject chemical, effect of pH conditions, rates of reactions, estimation of solubility in water under specified conditions, evaluation of specific behavioral characteristics of a substance (e.g., likelihood that a substance will cause foam in a natural aquatic environment), further detailed analysis of the intended use(s) and of other potential uses, classification of chemicals from the standpoint of structure or function, detailed identities and levels of impurities, byproducts, and other associated substances, PBT substances, and the potential for pollution reduction or pollution prevention. The completion schedule to complete detailed review chemistry reports will vary depending on the amount of information desired and the difficulties encountered in obtaining it (completion within two to three weeks is typical). Standard review chemistry reports, electronic version written in the prescribed format, currently Corel Word Perfect (latest version), are to be delivered to EPA WAM. The contractor may also be required to interact with other OPPT review staff and to participate in Standard Review workgroup meetings as they may occur.

3. Follow-up Review, PMN Reports

These Chemistry reports on PMNs provide the technical basis for additional evaluations, such as the prediction of significant new uses as required by Section 5 of TSCA. The Agency will identify specific PMNs for which these chemistry reports are required and establish due dates, usually within one week. The contractor shall review, gather, develop, and evaluate all pertinent chemical information that may assist the Agency in its decisions. For example, in the case of developing significant new uses, the contractor shall thoroughly evaluate the intended uses and provide data and technical insight on the intended uses during the initial commercialization. The information should be of sufficient clarity and completeness that it is readily understood by nontechnical personnel and that the information on the intended uses represents a sound baseline from which to make predictions. The reports must also provide clear rationale for alternative commercialization scenarios (i.e., potential other uses or "significant new uses" and their likelihood).

Predictions and rationale in these reports shall be based on chemical type, structure, composition, chemical properties, physical properties, data on analogs, or an end use effect derived from the scientific literature or relevant data bases as well as first hand knowledge, experience and professionally based judgment.

4. Existing Chemical Reports:

The contractor shall gather, develop, or validate specific, in-depth chemical information on existing chemical substances, classes, or subclasses of existing chemicals assigned for review. EPA will initiate each existing chemical task by identifying the subject chemical or group of chemicals in a detailed scope of work statement. The tasks vary widely in terms of the type and amount of information required, but all such requests will involve chemistry and chemical technology information.

The contractor may also be required to provide support requiring similar kinds of chemistry review and analysis as described in tasks 1 through 6 under TSCA, SARA and/or PPA, as well as other laws administered by EPA. Such support will be described in work assignments if and when the need for such work arises. Examples of past tasks are: (1) systematic grouping and ordering of chemical substances that are pending review to gain efficiency and to set priorities for review; (2) retrieval of specific information from Premanufacture Notices, statistical analysis, and summary of information as well as recommendations directed toward responses to petitions for exemptions to Section

5(a) of TSCA or to submitted public comments related to proposed exemption rule making; (3) application of "knowledge-based" technology; (4) discussing the development and availability of new methods which support chemistry evaluations of new and existing chemicals; and (5) development of summary chemistry reports for sets of closely related chemical substances that have been reviewed under Section 5 of TSCA or under Title III of SARA.

The contractor shall also be required to support other initiatives within OPPT, such as the Design for the Environment, High Production Volume (HPV) chemicals, Use Cluster, Pollution Prevention, and Green Chemistry. Technical support may include performing screening-level risk assessments and hazard assessment reports, as directed by the Work Assignment Manager. Technical direction will specify the chemicals or groups of chemicals to be assessed. The contractor shall review the list of chemicals submitted and verify that the names and CAS numbers match and are correct. For each chemical or group of chemicals, profiles shall be prepared that include such information as identity, physio-chemical properties, chemical fate profiles, PBT potential, and a hazard assessment. The contractor should consult data sources such as: Chemical Abstracts, Beilstein, Environmental Fate Database, Hazardous Substance Database, Cincinnati Risk Reduction Engineering Lab, Treatability Database, IRIS, RTECS, Chemfate, Toxline, Genetox, Aquire, Phytotox, and Terretox. Reports will be delivered in the prescribed format in both hard and soft copies and may require both CBI and non-CBI versions.

5. Pollution Reduction/Prevention Assessments

The New Chemicals Program of OPPT provides EPA with an opportunity to foster pollution reduction or pollution prevention at the source for industrial chemicals, i.e., in the actual manufacturing process for a new chemical. It is important to utilize pollution reduction and pollution prevention concepts and ideas explicitly in the New Chemicals Program. In addition to providing a review of PMNs for establishing the identity of the PMN substance, its physical/chemical properties, and basic chemistry, the contractor shall also provide an assessment of the character and amount of wastes produced from the manufacturing processes of PMN substances preselected by EPA following a prescribed selection process. The information called for in the PMN submission and provided by the submitter will be compared to a set of chemical parameters as a preliminary assessment of the amounts and types of wastes associated with a given manufacturing process. The contractor shall also prepare a detailed assessment on certain PMN chemicals selected by the EPA, describing possible causes of the waste produced and suggest approaches for its reduction and/or process alteration. The contractor shall design

methods for incorporating process chemistry parameters and potential alternative synthetic steps, pathways, feedstocks, catalysts, etc. into the pollution reduction/prevention assessment, so as to enable retrieval of information based on selected key words, such as reaction type or function.

Preliminary assessment, using prescribed models and tools, is conducted as an adjunct to the initial chemistry review of the PMN substance. EPA WAM and/or staff chemists will determine whether a detailed assessment is necessary. The detailed assessment performed by the contractor will provide the technical information necessary for EPA to formulate recommendations to the submitter for waste reduction or elimination. In the pollution reduction/prevention review, the work performed by the contractor must be completed within one week of being assigned, whether a preliminary or detailed review, including oral presentation.

In depth analysis into the use, release, life cycle, and ultimate fate of the chemical in review, including PBT concerns and other alternatives, will be reviewed and reported.

6. Physicochemical Property Data for New Chemical Substances

EPA is responsible for the identification or estimation of chemical properties for PMN substances which are in question or not provided by the PMN submitter. The contractor shall prepare reports which identify empirical physical and chemical data, such as water solubility, for a wide range of chemicals which is to be used as a source for analogs. Existing empirical data should be obtained from published literature, reference volumes, industrial literature and other commercial sources. The contractor shall use professional judgment as to the validity and empirical nature of the information in all cases. Results and updates shall be delivered by the contractor to EPA each month or as required by EPA. The report shall include chemical structure, CAS Registry Number, the empirical values, including the temperature at which they were measured, and the references. Values such as melting point, boiling point, vapor pressure, octanol/water partition coefficient, pH, and salinity, if found are to be included. The contractor shall also provide quality control of information and structures provided. This shall include the assurance through cross-checking that no duplicative work is done on chemicals that are already available, unless the new work corrects or completes existing information.

7. Tool and Model Development

OPPT develops and maintains a broad range of computerized methods, models, and tools used internally in support of new

chemicals, existing chemicals, and pollution prevention programs as well as by external customers. These products include, for example, databases for tracking pollution prevention technologies, methods for existing physical/chemical properties, models for determining exposure scenarios, and tools for evaluating risk from chemical releases. It will be necessary for the contractor to provide support for OPPT's methods, models, and tool development in the form of data collection, programming, maintenance, and outreach. This support may also include web site development and maintenance.

The contractor shall provide necessary support described in the work assignment when the need for such work arises. This may include skills such as HTML editing and web site production and programming in a variety of languages, such as Visual Basic and C++.

All software and web sites must conform to Agency standards. In addition, software, documentation, and web sites should be designed to be accessible to users with disabilities whenever possible.